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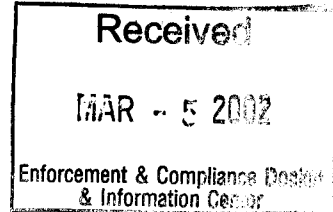


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U.S. Environmental Protection Agency  
Enforcement and Compliance Docket and Information Center  
Mail Code 2201A  
Attn: Docket Number EC-2000-007  
1200 Pennsylvania Avenue NW  
Washington, DC 20460



Dear Sir or Madam:

Monsanto Company is pleased to comment on the Agency's proposed Cross-Media Electronic Reporting and Record Keeping Rule (CROMERRR), which was published in the Federal Register, Vol. 66, No. 170 on August 31, 2001. Monsanto Company is a global manufacturer and supplier of agricultural products, with many facilities within the United States that are subject to EPA reporting and record-keeping requirements. Enclosed with this letter, Monsanto respectfully submits our comments for your consideration. The comments on CROMERRR are arranged in order of appearance in the Preamble and the Rule itself.

Monsanto welcomes efforts of the EPA to move in a direction that enables electronic reporting and record keeping. However, Monsanto believes that the Proposed Rule, as written, will pose significant undue financial burden and resource burden on the regulated community that is not accurately articulated in the CROMERRR Preamble or Proposed Rule. Other key areas of concern include a lack of clarity regarding the voluntary nature of the Proposed Rule and a lack of consideration given to the unique needs and processes of the FIFRA-regulated community, particularly regarding record-keeping requirements. Monsanto also strongly supports the formation of a Working Group on CROMERRR that would collaborate to resolve issues prior to publication of the final CROMERRR Rule. We urge that this Working Group be formed and include participation from all stakeholders, including representatives from companies submitting registration applications to EPA under FIFRA. Alternatively, we would ask EPA to consider omitting the record-keeping provisions until these significant issues can be adequately addressed.

Thank you for the opportunity to submit comments.

Sincerely,

Mark E. Holland, Ph.D.  
Director, Regulatory Sciences  
(636)737-6409

## **PREAMBLE**

### **I Overview B. What will the proposed regulations do?**

(1) **Comment 1:** According to EPA FIFRA GLP (40 CFR Part 160) and TSCA GLP (40 CFR Part 792), there are “other” records that relate to the predicate rule that are required to be maintained – in addition to the GLP data used to report the results in a final report that is part of a submission to EPA. Examples of these records are: facility records, master schedules listing the status of GLP studies, equipment maintenance records, training records, SOPs. These “other” records may be a combination of electronic and/or paper records. We recommend that CROMERRR clarify whether these “other” EPA FIFRA GLP (40 CFR Part 160) and TSCA GLP (40 CFR Part 792) records are required to be covered and included in CROMERRR.

**Justification:** It is unclear whether the “other” records required under EPA FIFRA GLP (40 CFR Part 160) and TSCA GLP (40 CFR Part 792) are meant to be included as part of CROMERRR.

### **I Overview B. “For regulated entities that choose to keep records electronically, today’s proposal requires the adoption of best practices for electronic records management.”**

(2) **Comment 2:** We recommend that EPA clarify the term “best practices for electronic records management”.

**Justification:** The development and maintenance of electronic records processes and systems represents a significant investment for regulated entities. In order to adopt best practices, these practices must be clearly defined.

(3) **Comment 3:** The expectation of the EPA as to whether best practices should be in place in order for a regulated entity to be considered in compliance with CROMERRR, or whether the regulated entity may demonstrate development of “best practices”, as an ongoing goal, should be specified.

**Justification:** Clearly stated expectations will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

## **II. Background**

### **B. How would today’s proposal change EPA’s current electronic reporting policy?**

**“In terms of electronic signature technology, while we may continue to allow PIN-based approaches, our plan is to emphasize digital signatures based ‘public key infrastructure’ (PKI) certificates, given the increasing support for – and acceptance of – PKI for commercial purposes.”**

(4) **Comment 1:** Please provide a time frame and technical implementation criteria regarding when and how EPA plans to emphasize PKI certification and digital signatures and how PIN-based approaches will be treated under this scenario.

**Justification:** In discussions with IT personnel PKI implementation implies legal ramifications for data ownership and patent issues. It will be important, therefore, to preserve the option for PIN-based approaches going forward.

(5) **Comment 2:** A typical FIFRA (40 CFR Part 160) compliant submission includes many records and reports, each of which are required to bear signatures of several individuals who attest to various responsibilities as dictated by the FIFRA regulation. Please consider whether CROMERRR anticipates and

provides for receipt of the large numbers of digital signatures (perhaps up to 80) that are typically associated with one submission.

**II. E. What information is EPA seeking about electronic reporting and record-keeping proposals? "EPA is seeking comment whether today's proposal will make electronic reporting and record-keeping a practical and attractive option for smaller regulated entities, especially small business."**

(6) **Comment 1:** Small companies that perform work under FIFRA GLPs have embraced electronic systems for data collection and recording in order to perform modern methods, and to increase productivity. If these systems are not CROMERRR compliant, or are not capable of CROMERRR compliance, these small companies must incur additional costs for equipment upgrades, or return to paper-based systems. In fact, some analytical methods cannot be performed without the use of computer-based systems. In that case, there is no "paper option". These alternatives, the lack of an equivalent paper-based system and substantial additional equipment costs, create significant business obstacles for small companies. Electronic record-keeping requirements, more than reporting, present a significant challenge for small business.

**Justification:** While Monsanto and other large companies may be better able to absorb large expenses associated with system upgrades required by CROMERRR, small businesses will likely find it impossible to bear the financial burden of the proposed record keeping requirements. Monsanto relies on many small businesses to provide a wide variety of data, much of which is already being gathered electronically that ultimately become part of the information that is required by EPA for product registration and maintenance. If small business cannot provide CROMERRR-compliant data and/or reports, Monsanto will also be greatly affected. Small companies may be unfairly disadvantaged in the marketplace. Any rule requiring such large expenses must offer commensurate benefits. It is not clear that this rule offers those benefits.

(7) **Comment 2:** The agency's definition of raw data is key in assessing whether CROMERRR is a practical option for small businesses. If paper print outs of electronically captured data can be considered raw data, then regulated entities can choose how best to maintain and retain records that are authentic and trustworthy. If paper printouts of electronically captured data cannot be considered raw data, then CROMERRR is not a practical or attractive option for small businesses. We recommend that the EPA consider severing the records keeping aspect of CROMERRR until these issues can be thoroughly addressed with key stakeholders.

Please clarify the Agency's position regarding the application of CROMERRR regarding electronic versus paper capture of raw data. There are two potential interpretations of the rule regarding this issue, illustrated in the examples below.

The Agency has stated that the electronic record-keeping side of CROMERRR will apply only if submitters choose to use electronic record-keeping. It might be interpreted that data could be captured with current instrumentation which creates an electronic file output and, by SOP, one could define the raw data as the paper printout of the electronic version and delete, when appropriate, the original electronic file. The signed and dated paper copy of the raw data could still be managed under the pre-CROMERRR regulations for maintaining paper raw data. The original electronic file could still be used to process the data into results that would be captured in an electronic report. The results in the report could be audited against the paper raw data to insure that the final results represent the original raw data. The electronic report could then be submitted electronically, when the Agency is ready to receive such, according to criteria in the electronic document submission side of CROMERRR.

Another interpretation is that if the original data capture is electronic and this electronic file is processed electronically with some software application, then under CROMERRR one would define the raw data as the electronic file(s) and comply with all electronic record-keeping provisions of this proposed rule, and will not have the option of defining the raw data as the signed and dated paper copy of both the original

electronic raw data file and any calculated results electronic files. In this case, the act of electronic capture of data forces one to follow the electronic record-keeping rule.

**Justification:** The proposed CROMERR Rule states in several locations that compliance with the CROMERR Rule is strictly voluntary. However, EPA's definition of raw data, both in CROMERRR and all underlying EPA program regulation, is key to achieving a truly voluntary regulation. The voluntary nature of CROMERRR is addressed in many places in EPA's proposal; some examples follow.

- Summary: "Under today's proposal, electronic document submission or electronic record-keeping will be totally voluntary; EPA will not require the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records."
- p. 5: "... These proposed requirements will apply to regulated entities that choose to submit electronic documents and/or keep electronic records, and under today's proposal, the choice of using electronic rather than paper for future reports and records will remain purely voluntary . . . ."
- p. 13: "... Under today's proposal, the entities that can use electronic reporting and record-keeping will not be required to do so; they can still use the medium of paper for document submissions and records if they choose. . . ."

We feel that the fact that modern laboratory instrumentation produces an electronic file output should not mandate electronic record-keeping. Please clarify if the draft CROMERR Rule supports this interpretation. Alternatively, please consider postponing the adoption of the record-keeping part of CROMERRR until these questions can be addressed.

**II. E. What information is EPA seeking about electronic reporting and record-keeping proposals?  
"EPA is interested in concerns or issues that commenters may wish to raise about the effect that moving from paper to the electronic medium may have on the compliance structure."**

(8) **Comment 1:** Please detail EPA Office of Compliance plans for administering compliance monitoring and guidance activities, since the implementation of CROMERRR will require significant EPA resources.

**Justification:** EPA suffered significant personnel cutbacks in the last decade such that the Draft Merged FIFRA/TSCA GLPs are "on hold" indefinitely. Monsanto is concerned that EPA will have insufficient resources to train inspectors, provide guidance documents for industry and assure compliance.

(9) **Comment 2:** We recommend that EPA generate compliance guidance for regulatory inspectors and for the regulated community that is consistent with the following EPA and FDA documents:

FDA Compliance Policy Guide 7353.17 (enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures); FDA Compliance Program Guidance Manual, Program 7348.808 – Chapter 48 – Bioresearch Monitoring, Good Laboratory Practice (Nonclinical Laboratories); FDA Compliance Program Guidance Manual, Program 7348.808s – Chapter 48 – Bioresearch Monitoring, Good Laboratory Practice Program (Nonclinical Laboratories), EPA Data Audit Inspections; EPA Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act Good Laboratory Practice (GLP) Regulations, Envires Ref#: P4073; EPA Final TSCA GLP Enforcement Response Policy, Envires Ref#: P2024.

**Justification:** Consistency regarding agency inspection for compliance with FDA 21CFR Part 11 and CROMERRR will facilitate industry compliance. EPA can maximize resources by exploiting the similarities with FDA's requirements, guidance documents and inspection experience for electronic record keeping systems.

**III. C. EPA believes that receipt of electronically transmitted confidential business information (CBI) requires considerably stronger security measures than the initial version of CDX may be able to support, including provisions for encryption.**

(10) **Comment 1:** We believe that CBI should be transmitted only if the CDX includes provisions for encryption. Furthermore, we believe that all information transmitted over the internet should be encrypted.

**Justification:** Without encryption, any information transmitted over the internet will not be secure. One of the key goals stated in this legislation is accountability of electronic data (trustworthy, reliable and generally equivalent to paper records) for submitted data. Individuals and organizations cannot be held accountable for unsecured data submitted over the internet unencrypted. Hence, encryption will have to be in place regardless of whether or not the data is "confidential business information."

### **III. C. EPA seeks comments on this proposal's global approach, and whether specific exclusions should be added to the rule.**

(11) **Comment 1:** We recommend that the Agency consider excluding FIFRA reporting until the Agency meets with the regulated community to discuss the particular concerns of FIFRA GLP groups. An alternative to transferring FIFRA submissions over the internet might be to transfer the information via CD technology. An example of this type of data transfer is currently in use at EPA's Office of Pesticide Programs (OPP). OPP is currently exempted from CROMERRR due to their use of magnetic media; a similar exemption for FIFRA submitters should be considered.

**Justification:** FIFRA studies can include quite a large amount of data. At this time it is unclear whether transfer of FIFRA submissions via the internet would be successful and secure.

### **III. C Which documents could be filed electronically? EPA seeks comments and advice on priorities for electronic reporting implementation.**

(12) **Comment 1:** In no instance should the transmission of any data/reports/CBI occur until the CDX system has been adequately tested, evaluated and certified as effective and reliable.

**Justification:** We believe that there needs to be a distinction between electronic record keeping (directed by predicate rules) electronic reporting of data and confidential business information (CBI).

Electronic reporting options should be explored independent of electronic record keeping which is potentially non-voluntary due to predicate rule requirements. EPA should work closely with the FIFRA regulated parties to fully understand the amount of data required for submission of documents and only implement electronic reporting after case studies have been completely researched. The interaction between the Agency and the FIFRA regulated parties should also explore the timing of data submission and the possibility of excluding the information from the agency's global approach.

We agree that submission of CBI data is a special category and must only be attempted after careful review and testing of the CDX capabilities, especially for encryption.

### **IV. A. EPA...seeks comment on the appropriateness of the time-frame for notice of major changes.....and whether it is in the best interest of the EPA and regulated entities to codify these public notice provisions.....and whether the different cases are or can be defined with sufficient precision....**

(13) **Comment 1:** We believe that the time frames are appropriate, necessary and should be codified.

**Justification:** We believe any changes to the CDX design may have unknown implications for different regulated entities and, although EPA will have a strong understanding of the capabilities of the CDX, EPA may not be able to predict its impact on other systems.

Without specified and codified notification and time periods, changing technology could warrant continuous and frequent changes to the submission process. That could lead to confusion and increased/repeated and unnecessary costs to the EPA as well as the regulated community.

(14) **Comment 2:** EPA may want to re-consider making judgments on effects of changes and design one system of notification for all regulated parties.

**Justification:** One concern of the regulated community is the EPA's assertion that major changes "will not generally include optional upgrades to software, the provision of additional formatting (or other technical) options, or changes to CDX that simply reflect changes to the regulatory reporting requirements that the system is supporting;" How will the EPA determine whether or not an upgrade is "optional"? For example, will a considerable business advantage warrant an upgrade? Furthermore, the involved parties may come to different conclusions about whether an upgrade is truly "optional" differently.

**IV. B. 1. These criteria are designed to insure that electronic records are trustworthy and reliable, available to EPA and other agencies and their authorized representatives in accordance with applicable federal law, and admissible as evidence in a court of law to the same extent as a corresponding paper record." See also §3.2000 (b) "An acceptable electronic document receiving system must generate data sufficient to prove, in private litigation, civil enforcement proceedings, and criminal proceedings..."**

**PREAMBLE IV.B.(1) and (2) : Regulated entities that use electronic systems to create, modify, maintain, or transmit electronic records will need to employ.....EPA's proposed criteria for electronic record-retention systems must: 1) generate and maintain accurate and complete copies of records and documents in a form that does not allow alteration of the record without detection;...**

**EPA seeks comment on whether these criteria are appropriate; sufficient to ensure that signatures associated with records fulfill their purpose, and whether these criteria are appropriate for the maintenance of electronic records containing *digital* signatures.**

(15) **Comment 1:** Are these criteria identical to those in 21CFR, Part 11? How will EPA CROMERRR requirements be aligned with FDA Part 11 requirements?

**Justification:** Many regulated entities are required to comply with electronic records and reporting regulations from both EPA and FDA. Harmonization of these two rules is highly desirable for administration and management purposes, as well as to contain costs.

(16) **Comment 2:** Will EPA seek to interpret CROMERRR in a similar way as FDA has interpreted 21 CFR Part 11, regarding compliance expectations and inspection conduct?

**Justification:** Experience gained in working toward compliance to Part 11 by regulated entities should be applicable to implementation of CROMERRR. For example, technical limitations regarding long term archival of electronic records have made compliance to Part 11 particularly challenging. Consideration of areas where there may be a gap between agency expectations and technical capabilities is requested.

**IV. (B)(6) Additional Options...We realize that the electronic records criteria in today's rule are not as detailed as that contained in FDA's 21 CFR Part 11 and seeks comments on whether our proposed criteria are sufficient to ensure the authenticity...**

(17) **Comment 1:** We recommend that the requirements in today's proposal be reworked so that they are closer in scope and implementation to 21 CFR Part 11 so that industry can develop a single compliance program that will satisfy both EPA and FDA electronic records requirements. A lack of some of the

provisions in CROMERR, as defined in Part 11, could undermine the evidentiary value of an electronic record.

(18) **Comment 2:** We recommend that the conversion of paper records to electronic forms be addressed.

**Justification:** If electronic records are to be the storage medium of choice in the future, acceptable methods for the conversion of paper documents to an electronic form must be developed. Since some predicate rules require retention for many years' conversion, retention and migration parameters should be defined. Even if current technologies do limit this ability CROMERR should not disallow this as an option so long as the appropriate criteria are met.

**C. 6 System Archives.** EPA also proposes to require that electronic document receiving systems maintain the contents of the *transaction record* described above.... EPA seeks comments on these archiving criteria, and especially on whether there are any issues raised by the need to maintain the *copy of record* – which includes electronic signatures – over long periods of time.

(19) **Comment 1:** Ensuring the trustworthiness of electronic signatures over long periods of time is addressed in "Records Management Guidance for Agencies Implementing Electronic Signature Technologies," National Archives and Records Administration, October 18, 2000. In particular, the NARA has recommended two possible approaches in section 4.3 of this document:

*One approach:* An agency may choose to maintain adequate documentation of the records' validity, such as trust verification records, gathered at or near the time of record signing. This approach requires agencies to retain contextual information to adequately document the processes in place at the time the record was electronically-signed, along with the electronically-signed record itself. The additional contextual information must be retained for as long as the electronically-signed record is retained. Thus the agency preserves the signature's validity and meets the adequacy of documentation requirements by retaining the contextual information that documented the validity of the electronic signature at the time the record was signed. Maintaining adequate documentation of validity gathered at or near the time of record signing may be preferable for records that have permanent or long-term retentions since it is less dependent on technology and much more easily maintained as technology evolves over time. However, using this approach, the signature name may not remain readable over time because of bit-wise deterioration in the record or as a result of technological obsolescence. Agencies must ensure that for permanent records the printed name of the signer and the date when the signature was executed be included as part of any human readable form (such as electronic display or printout) of the electronic record.

*Another approach:* An agency may choose to maintain the ability to re-validate digital signatures. The re-validation approach requires agencies to retain the capability to revalidate the digital signature, along with the electronically-signed record itself. The information necessary for revalidation (i.e., the public key used to validate the signature, the certificate related to that key, and the certificate revocation list from the certificate authority that corresponds to the time of signing) must be retained for as long as the digitally-signed record is retained. Both contextual and structural information of the record must be retained, as described in Section 4.2. This approach is potentially more burdensome, particularly for digitally-signed records with long retention needs, due to issues of hardware and software obsolescence. If an agency chooses this approach for permanent records, it must contact NARA to discuss what they will need to do to transfer the records to NARA. As in the first approach, the agency must ensure that the printed name of the electronic signer and the date when the signature was executed be included as part of any human readable form (such as electronic display or printout) of the electronic record.

We recommend adoption of the first approach.

**Justification:** (1) Adoption of this approach would be consistent with NARA recommendations; and (2) there are currently no known technological solutions that adequately support re-validation of digitally-signed records over long retention periods.

(20) **Comment 2:** 40 CFR Part 160 (FIFRA) regulation requires archival of all records and reports for the life of product registration, much longer than FDA archiving requirements, and lasting 30 years or longer. EPA should consider the additional option of conversion of electronic records to paper for archival purposes.

**Justification:** While technology remains untried and untested, regulated entities will continue to archive paper records. Therefore CROMERRR will not achieve paperwork reduction with regard to the archival of electronic records and electronic reports.

**VI. E. Unfunded Mandates Reform - Act, paragraph 3 "...this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local and ... or in the private sector in any one year..."**

(21) **Comment 1:** We ask EPA to better assess the financial burden of complying with this regulation.

**Justification:** We believe that the assertion that the rule is "voluntary" and that this rule will not mandate excess expenditures exists in theory only. The reality is that electronic systems are already being used and in order to comply with this rule, expenditures in gap and risk analyses, upgrading software, and purchasing new systems where others do not comply will place a sizeable burden on industry.

Based on Monsanto's recent experience with the implementation of a chromatography data system (CDS) with features that address requirements of the CROMERRR rule, system support for 150 channels of identical data required nearly \$1 million in expenditures for hardware and software. Validation costs and annual support agreement costs added \$45K and \$120k respectively. Additional costs for a long term archival will approach \$150k with annual support costs of \$20k. Additional costs for future software and hardware upgrades, validation and the cost of preparing documents for electronic submission are not included. These costs far exceed the EPA projected costs and this is just one of many systems at one facility that would require upgrades to be CROMERRR compliant.

## **CROMERRR RULE**

### **§3.1 Scope:**

(22) **Comment 1:** This paragraph describes the conditions for satisfying requirements that include "maintenance of electronic records." We recommend clarification to specify whether "generation" of records is included in the scope of this rule..

**Justification:** While "generation" of records may be implied, clarification would improve consistency in implementation

### **§3.3 Definitions, Electronic document receiving system**

(23) **Comment 1:** This definition describes receiving systems without mentioning state programs or certified systems. Please clarify whether all electronic document-receiving systems must be certified, whether they are part of a state program or belong to private industry.

**Justification:** Clarification of which systems must be certified will reduce potential delays in implementation and remove the burden from the Agency of repeatedly clarifying the issue.

### §3.3 Definitions

(24) **Comment 1: Digital signature is not defined. We recommend defining the term.**

**Justification:** The term “digital signature” is used in both the Preamble and the Proposed Rule. Clarification of the Agency’s definition associated with the term will reduce confusion facilitate implementation of compliance plans by the regulated community.

**§ 3.3 Definitions – Electronic record-retention system means any set of apparatus, procedures, software, records or documentation used to retain exact electronic copies of electronic records and electronic documents.**

(25) **Comment 1:** EPA FIFRA, 40 CFR 169.2(k) concerning data and records requires all “original” data to be maintained for the length of the product registration (which may be greater than 30 years). We recommend OEI contact the EPA FIFRA office in charge of 40 CFR Part 169 and clarify if the migration of records, meeting CROMERRR’s criterion for the migration, will be acceptable as maintaining “original” records and that “original” paper records retention, implicit in 40 CFR Part 169, is nullified by the issuance of CROMERRR.

**Justification:** With the data requirements in EPA FIFRA 40 CFR 169.2(k), it is unclear whether migrated data, as implied in CROMERRR, would meet the requirements of 40 CFR Part 169.

(26) **Comment 2:** We recommend modifying the definition for “electronic record-retention systems” from “used to retain copies” to “used to maintain exact copies”.

**Justification:** With EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792), records are maintained after collection and not retained until formally archived. This wording change would clarify this situation.

(27) **Comment 3:** We recommend addition of a definition for “exact electronic copy”. Please define criteria for this term.

**Justification:** There is confusion over what exact electronic copy means and what kind of verification process would be required under CROMERRR.

**§ 3.3 Definitions - Electronic signature device means a code or other mechanism that is used to create electronic signatures. Where the device is used to create an individual’s electronic signature, then the code or mechanism must uniquely belong to or be associated with or assigned to that individual. Where the device is used to create an organization’s electronic signature, then the code or mechanism must uniquely belong to or be associated with or assigned to that organization.**

(28) **Comment 1:** This definition appears to imply that a device is *required* to create electronic signatures. Please clarify what is meant by “device” and whether such device is required for electronic signatures that are used in the maintenance of electronic records required by Title 40, but are not submitted to the Agency electronically. For example, would a UserID and password be considered an electronic signature device, or is a device something more complex?

**Justification:** The definition of an electronic signature device as a “code” or “other mechanism” causes confusion and requires clarification.

**§ 3.10 (b) Electronic documents submitted to EPA to satisfy a federal environmental reporting requirement or otherwise substitute for a paper submission permitted or required by a federal environmental program must be submitted to either: (1) EPA's Central Data Exchange; or (2) Another EPA electronic document receipt system that the Administrator may designate for the receipt of specified submissions.**

(29) **Comment 1:** We recommend that, for the EPA FIFRA GLP (40 CFR Part 160) and TSCA GLP (40 CFR Part 792) submissions, the submitter registration process be acceptable on an individual company basis that submits the registration on behalf of all companies that may have participated in the studies included in the submission.

**Justification:** In the case of EPA FIFRA GLP and TSCA GLP reports, there will be many electronic signatures in one report, and many reports in one FIFRA or TSCA registration filing with EPA. By making the submitter registration process acceptable on an individual company basis for EPA FIFRA and TSCA GLP registration filings, there will be far less tracking, resources, and burden on both EPA's and industry's part. This will still result in placing responsibility for the filing on the individual company, and in complying with CROMERRR.

(30) **Comment 2:** We recommend that CROMERRR establish a different CDX prototype process for handling EPA FIFRA GLP (40 CFR Part 160) and TSCA GLP (40 CFR Part 792) submissions.

**Justification:** This is suggested because of the size of a typical EPA FIFRA or TSCA GLP submission (e.g., a typical FIFRA submission may be 56,000 pages or 1,300 megabytes of data), unlike the CDX used for state submissions.

(31) **Comment 3:** We recommend that provisions be made for CDX to accommodate CBI (confidential business information) submissions from FIFRA/TSCA submitters. CBI is a major part of FIFRA submissions and the information must be protected.

**Justification:** These provisions are requested because CBI will typically be a part of the EPA FIFRA GLP (40 CFR Part 160) and TSCA GLP (40 CFR Part 792) submissions. If CBI submission security were not in place at CDX, Monsanto would be most likely to continue to submit paper documents, rather than use CDX.

**§ 3.10 (b) (2) – Electronic signature must meet the validation requirements of the electronic document receiving system to which it is submitted.**

(32) **Comment 1:** Please clarify the meaning of the term "validation." When considered in the context of electronic systems and electronic records, the term "validation" generally applies to a process used to ensure consistent intended performance of a computer system. It is recommended that the term "validation" should be included in § 3.3 Definitions, and the validation requirements should be explicitly presented or referenced.

**Justification:** This could be confusing to submitters.

**§ 3.20 How will EPA provide notice of changes to the Central Data Exchange?**

(33) **Comment 1:** We recommend that EPA clarify what the backup procedure will be for the Central Data Exchange and the procedures that will be followed when the system is not operational (down).

**Justification:** Although the rule addresses notification of the public for planned changes to the CDX or another EPA electronic document receiving system, it does not indicate how the CDX system will be backed up to protect against the loss of data/reports submitted to EPA. Since electronic documents can only be submitted to this system, there should be procedures in place to let submitters know when the

system is down and how submissions should be made during that time period, e.g., use of another receiving system, notification of users when the system is operational again so they can resume submission activities, etc.

**§ 3.20 (2)(b) Any change the Administrator determines is needed to ensure security and the integrity of the Central Data Exchange is exempt from the provisions of paragraph (a)**

(34) **Comment 1:** Sufficient testing of CDX must occur before documents are deemed ready for submission. All security issues must be addressed. If paragraph (a) is exempted in certain situations then alternative methods for submission must be available. A change in CDX may cause the submitter to change the way they submit.

**Justification:** The submitter needs time to verify and validate any changes in order comply with CROMERRR.

**§3.100 (a)(1) Generate and maintain accurate and complete electronic records and documents in a form that may not be altered without detection.**

(35) **Comment 1:** It is requested that EPA clarify any requirements, in addition to a secure audit trail, that would need to be met to satisfy this requirement.

**Justification:** According to this section of the rule, an electronic record or electronic document will satisfy a record-keeping requirement of an EPA administered federal environmental program under this title only if it is generated and maintained by an electronic record retention system as specified under this subsection. EPA should clarify any additional controls that they would consider necessary to preserve the integrity of electronic records and documents. The burden and cost to industry in implementing controls should be taken into consideration when determining the need for such practices in the final rule.

**§3.100(a)(2) Maintain all electronic records and electronic documents without alteration for the entirety of the required period of record retention;**

(36) **Comment 1:** Section 3.100(a)(2) is adequate as written to assure the integrity of electronic records.

**Justification:** The specification of a particular technology is counterproductive—e.g. error checking will not address metadata. We support a performance-based approach.

**§3.100(a)(3) ...accurate and complete copies ....in both human readable and electronic form.....for the entirety of the required period of record retention.**

(37) **Comment 1:** EPA FIFRA GLPs (40 CFR Part 160) and TSCA (40 CFR Part 792) retention times can be very long, e.g. for 10 to about 30 years, whereas FDA GLPs (21 CFR Part 58) retention times are 2 to 5 years after submission to FDA in an application for research or marketing permit, (in the case of submitting a New Drug Application (NDA), this also can be a very long period of time). We recommend identifying a more liberal approach to records that must be retained for long extended periods of time. If migration of electronic records and reports is a solution to recovery over the record retention period, we recommend that OEI undertake a cost benefit analysis, before CROMERRR is finalized, of the impact of migrating data under CROMERRR in an EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792) environment.

The scope of information required in human readable form should be addressed. Significant additional reporting not currently available would be required to present all of the information in the electronic record as an electronic document, including such items as signal voltages and metadata.

We additionally recommend that EPA consider working with industry representatives, the EPA Office of Enforcement and Compliance, as well as FDA on resolving the issue of long-term recovery of electronic records and reports.

**Justification:** This presents a major difference between what is required for FDA's 21 CFR Part 11 on electronic records and what is required of industry by CROMERRR. It may mean that migration of the electronic records and reports, hardware, software, etc., will be required, since retaining obsolete hardware and software is impractical and in some cases impossible for recovery over the long extended retention periods required by some EPA or FDA predicate rule. Migration requires major acceptance testing and validation activity. This would be a massive and costly exercise to simply migrate the registration documents for only one chemical entity. Maintaining the metadata during migration is also a very difficult task.

(38) **Comment 2:** Please define "off-site" review. Does this mean access to a network by agency reviewers?

**Justification:** The ability to reproduce an electronic copy of a record or subset of records for off-site review can be a major implementation hurdle especially with more complex electronic record-keeping systems. For example, the ability to export a record may be straightforward but exporting accompanying metadata, electronic signatures, and audit trails may be problematic. It may take significant time and programming resources to do a full export. It will also be difficult for companies to assess their ability to comply with this requirement without more specifications from the EPA on what type of file exports they will be able to review off-site. Significant costs could be incurred to provide for "off-site" review. More detail on what is required to meet this requirement is needed.

**§3.100(a)(4) Provide that any electronic record or electronic document bearing an electronic signature contain the name of the signatory, the date and time of signature, and any information that explains the meaning of the affixed signature;**

(39) **Comment 1:** Please clarify whether all electronic records or only those bearing an electronic signature must contain the specified descriptors.

**Justification:** This clarification would explain what is meant by electronic records.

(40) **Comment 2:** Suggest adding "printed" before the phrase, "name of signatory."

**Justification:** This clarification would explain what is meant by signatories.

(41) **Comment 3:** Please further explain the "time" requirement. Is it hour, or hour and minute, and is the local time where the work is being performed required?

**Justification:** This clarification in wording related to the "time" definition would dispel possible confusion about interpretation of this issue.

**§3.100(a)(6) Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records or documents;**

(42) **Comment 1:** Please further explain the "time" requirement. Is it hour, or hour and minute, and is the local time where the work is being performed required?

**Justification:** This clarification in wording related to the "time" definition would dispel possible confusion about interpretation of this issue.

(43) **Comment2:** Please consider changing the following phrase from "audit trails that automatically..." to "audit trails that, after final approval, automatically..."

**Justification:** With EPA FIFRA GLPs (40 CFR Part 160) and TSCA (40 CFR Part 792), electronic records and documents have to be "committed" before they become an "officially accepted" electronic record or document. This clarification in wording would allow this process to continue.

**§3.100(a)(8): ...records and documents are searchable and retrievable for reference and secondary uses. ..for the entirety of the required period of record retention.**

(44) **Comment 1:** Please define "secondary uses," and clarify what is meant by "available for legal proceedings and third party disclosures." Remove the word "searchable" since retrievable should address the availability of the records and documents.

**Justification:** It is unclear why industry must assure availability of records for government uses other than assuring to the agency the reliability and trustworthiness of the records. Searchable records require much more sophisticated and costly solution and may be impossible for some electronic files.

**§3.100 (a)(9)(ii): Related meta data can be transferred to a new system.**

(45) **Comment 1:** We recommend that OEI undertake a cost benefit analysis of the impact of migrating data under CROMERRR in an EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792) environment.

**Justification:** It is likely that migration of electronic records during the entire record retention requirement time will be necessary, since under EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792), retention periods vary from 10 to about 30 years. This required retention time is considerably greater than for FDA GLP records and should be considered when specifying migration and functionality for retained records.

Additionally, when migrating electronic records and documents to a new computer system, there is often no reasonable place to receive the meta data from the old system.

**§3.100 (a) (9) (iii): Functionality necessary for use of records can be reproduced in a new system;**

(46) **Comment 1:** We believe that the functionality required by archival material applies to the retrieval of records, rather than the use of records. Therefore, we recommend a wording change from "functionality necessary for use of records can be reproduced in a new system" to "functionality necessary for the retrieval of the records can be utilized in a new system."

**Justification:** The suggested wording change would be a more accurate reflection of retrieving the records in a new system. Please consider the record retention times (potentially as long as 30 or more years) and the changing technology that might place an unreasonable burden on industry to comply with such a requirement.

**§3.100(b) Computer systems (including hardware and software), controls, and attendant documentation maintained under this Part must be readily available for, and subject to, agency inspection.**

(47) **Comment 1:** Change the wording to, "Current computer systems (including hardware and software), controls, and attendant documentation ..."

**Justification:** The resources required to archive obsolete software and hardware, and assure that they will function properly at some future date, far outweighs any benefit derived.

(48) **Comment 2:** Change control is a desired mechanism for assuring that a system is managed in a way that assures changes to the system have been properly assessed and implemented. Does the term "controls" relate to change control? Please clarify.

**Justification:** There is confusion over the meaning of "controls".

(49) **Comment 3:** Legacy systems are not specifically addressed with respect to acceptable electronic records. We recommend that CROMERRR address what to do with legacy computer systems and related records. We suggest that legacy systems need to only be retained for a maximum of 5 years.

**Justification:** There will be a tremendous negative economic cost impact if regulated industry must maintain legacy computer systems as evidence of how electronic records or reports were available, at the time of collection.

**§3.2000 What are the criteria for acceptable electronic document receiving systems?**

(50) **Comment 1:** Please clarify how the criteria for electronic document receiving systems do or do not apply to electronic records systems that will not be used to submit an electronic document through an electronic document receiving system.

**Justification:** The electronic document receiving system may be classified according to FDA's 21 CFR Part 11 as an "open" system requiring application of encryption technology, submitter registration and electronic signature certification processes. However, we do not believe that such rigorous controls are necessary to ensure the integrity of data and attribution of electronic signatures applied to electronic records in "closed" systems where the organization responsible for the content of the electronic records has control of system access. Please consider defining "closed" and "open" systems and the controls associated with each.

**§3.2000 (a)(1) Have strong and effective protections against unauthorized access to the system;**

(51) **Comment 1:** More guidance on the minimum requirements needed to meet the "strong and effective" criteria is needed.

**Justification:** There may be a broad interpretation across industry of what constitutes "strong and effective protection" against unauthorized system access or foreseeable corruption or system compromise. Furthermore, "strong and effective protection against unauthorized system access" may not be possible under certain types of operating systems (e.g., Windows 98).

**§3.2000 (a) (2) An acceptable electronic document receiving system must: ...have strong and effective protections against the unauthorized use of any electronic signature on electronic documents submitted or received;**

(52) **Comment 1:** What sort of oversight will be employed to ensure these criteria are met for documents that are sent to EPA? Please describe the types of systems that will be used to monitor for unauthorized activities.

**Justification:** The security of submitted documents is a primary concern for regulated entities.

**§3.2000 (a) (4) Prevent modification of an electronic document once an electronic signature has been applied. (c)(5) Ensures that it is impossible to modify an electronic document without detection....**

(53) **Comment 1:** This requirement prohibits modification of an electronic document after an electronic signature has been affixed.

Please clarify how this requirement does or does not apply to electronic records to which an electronic signature has been affixed.

**Justification:** We agree that a record should not be modified after having been signed without the knowledge of the signatory; however, if circumstances arise where the record requires revision, an automatically generated audit trail for both the modifications and the repeated act of signing should adequately document the changes.

**§ 3.2000 (a)(6) Ensure that the system clock is accurate and protected from tampering or other compromise.**

(54) **Comment 1:** We recommend that more detail as to what the Agency means or requires should be given. Protecting the clock from tampering may be difficult depending on the operating system and whether it is client based or server based. The requirements described in the PREAMBLE V. The Central Data Exchange (CDX) Section 3. The CDX Architecture should be made uniform for the proposed CROMERR rule.

**§3.2000 (b) Validity of data**

(55) **Comment 1:** This section refers to ensuring that the document was actually submitted by the authorized signature holder: It appears this requirement applies to documents submitted through document receiving systems. Please clarify how this requirement will be applied to documents that contain numerous signatures, such as TSCA or FIFRA regulatory submissions that contain numerous reports with multiple signatures from potentially multiple sites in each report.

**Justification:** It is difficult to envision how this requirement would apply to the TSCA and FIFRA regulatory submissions without causing undo hardship on submitting organizations. Clarification will facilitate industry ability to comply with CROMERRR.

**§3.2000 (d) Submitter registration process**

(56) **Comment 1:** CROMERRR describes submission of electronic reports or electronic data through a certification process for state programs and systems. During the July 2000 CROMERRR meeting in Washington, DC, it was explained that no certification would be required for electronic reporting and record-keeping systems maintained by companies, operating under EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792), who submit reports directly to EPA.

We recommend that EPA clarify the issue of a CROMERRR certification process to be used or not used by companies operating under EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792) when companies submit reports directly to EPA.

**Justification:** It is unclear what CROMERRR certification process is to be used or not used by companies submitting reports directly to EPA when they are operating under EPA FIFRA GLPs (40 CFR Part 160) and TSCA GLPs (40 CFR Part 792),

(57) **Comment 2:** Has EPA conducted a cost estimation for the electronic submitter and signature registration process?

**Justification:** The cost to industry to implement a compliance program under 40 CFR Part 160 or 40 CFR Part 792 has been substantial, with estimates of 20-30% over conducting a pre-clinical study without

compliance to GLPs. Therefore, if an additional CROMERRR certification process cost is to be added to the cost of doing business, industry needs to know what is EPA's estimations of this added cost.

**§3.2000 (d)(4)(i) ...automatic and immediate revocation....any actual or apparent violation...**

(58) **Comment 1:** This section provides for an automatic revocation for actual or "apparent" violation of electronic signature agreement. We recommend that a process be defined for investigating and verifying "apparent" violations prior to any revocation action is taken.

**Justification:** While this may be appropriate for an actual violation, we believe this approach could result in unwarranted submission delays and possible loss of revenues if an "apparent violation" is the result of inaccurate or faulty reporting.

**§3.2000 (d)(5) Require that the registrant periodically renew his or her electronic signature agreement.**

(59) **Comment 1:** Delete 3.2000 (d)(5)

**Justification:** If appropriate verifications have been conducted as the acceptable electronic document receiving system and submitter registration process was established, an electronic signature should be valid for the length of employment. Therefore, the need to periodically renew or re-issue electronic signatures is not warranted. If the requirement for removal is not deleted, the cost of going through the renewal process should be determined prior to specifying a particular period of time for renewal.

**§3.2000(e) Electronic signature/certification scenario:**

(60) **Comment 1:** The certification of signatures with EPA is a very complex process compared to FDA 21 CFR Part 11 requirements. We recognize that these criteria apply to electronic documents submitted to electronic document receiving systems, but believe that clarification is needed around electronic signatures that are applied to electronic records within a "closed" system, one where access is controlled by the persons responsible for the content of the electronic records. EPA proposes to require that an electronic document receiving system must validate only electronic signatures that have been affixed after: 1) the submitter has scrolled through on-screen pages that present all the data to be certified in a familiar, human-readable format (§3.2000(e)(1)(i)). EPA is encouraged to meet with representatives of the FIFRA regulated community in order to assess and understand the volume of data involved with submission of documents for registration. The volume may be prohibitive for this situation.

**Justification:** We believe the complex electronic signature certification scenario described for electronic document receiving systems is burdensome and unnecessary for the integrity of data in closed systems. Furthermore, we believe that a process similar to that set forth in 21 CFR Part 11, where companies can send notification to FDA and have policies in place within their organizations that hold people accountable for their electronic signatures will suffice for the purposes of electronic signatures applied to electronic records in "closed" systems, as described above. Detection of scrolling through on-screen pages would probably require significant modification to most electronic document receiving systems, thereby imposing substantial cost and delay in ability to implement compliant systems. It is doubtful that this requirement would significantly add to the evidentiary value of the signature. Furthermore, this requirement appears to force a higher standard on signed electronic documents than what exists for paper documents.

This requirement is more stringent than current requirements and would produce an undue burden on the submitter when submissions that entail thousands of pieces of information are transmitted.

**§3.2000(g)(2)(i) Maintain the records ... for at least the same length of time as would be required for a paper document that corresponds to the received electronic document, and in a way that can be**

**demonstrated to have preserved them in their entirety without alteration since the time of their creation.**

**(61) Comment 1:** Specifically omit digital signatures from the maintenance requirement.

**Justification:** While the proposed EPA requirements are consistent with those published by the FDA in 21 CFR Part 11, the retention times set by the predicate rules are very different, and it is doubtful whether maintenance criteria for electronic records over extended retention periods can also be met for digital signatures. For example, David Fillingham notes that "Handwritten signatures can be verified in perpetuity, whereas digital signatures will likely become unverifiable after ten years or so due to data processing equipment and cryptographic standards obsolescence, certificate expiration, and other factors." (A Comparison of Digital and Handwritten Signatures, Paper for MIT 6.805/STS085: Ethics and Law on the Electronic Frontier, Fall 1997) - see <http://swissnet.ai.mit.edu/6805/student-papers/fall97-papers/fillingham-sig.html>).